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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/633,875	08/04/2003	Hassan M. Fathallah-Shaykh	047940-0148	5251	
	23524 7590 02/27/2007 FOLEY & LARDNER LLP			EXAMINER	
150 EAST GILMAN STREET			ZHOU, SHUBO		
P.O. BOX 1497 MADISON, W			ART UNIT	PAPER NUMBER	
,			1631		
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MONTHS		02/27/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

	Application No.	Applicant(s)				
Office Action Summary	10/633,875	FATHALLAH-SHAYKH, HASSAN M.				
Office Action Gummary	Examiner	Art Unit				
	Shubo (Joe) Zhou	1631				
The MAILING DATE of this communic Period for Reply	ation appears on the cover sheet w	ith the correspondence address				
A SHORTENED STATUTORY PERIOD FO WHICHEVER IS LONGER, FROM THE MA  - Extensions of time may be available under the provisions of after SIX (6) MONTHS from the mailing date of this commur  - If NO period for reply is specified above, the maximum statu  - Failure to reply within the set or extended period for reply widence and patent term adjustment. See 37 CFR 1.704(b).	ILING DATE OF THIS COMMUNION TO THE STATE OF THIS COMMUNION TO THE STATE OF T	CATION. reply be timely filed NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed	on <u>27 November 2006</u> .					
2a) This action is FINAL. 2b	o)⊠ This action is non-final.					
,						
closed in accordance with the practice	under <i>Ex parte Quayle</i> , 1935 C.E	). 11, 453 O.G. 213.				
Disposition of Claims						
4)  Claim(s) 1-35 is/are pending in the ap 4a) Of the above claim(s) 29-35 is/are 5)  Claim(s) is/are allowed. 6)  Claim(s) 1-28 is/are rejected. 7)  Claim(s) is/are objected to. 8)  Claim(s) are subject to restriction	withdrawn from consideration.					
Application Papers						
9)⊠ The specification is objected to by the 10)⊠ The drawing(s) filed on <u>04 August 200</u> Applicant may not request that any objection Replacement drawing sheet(s) including the 11)□ The oath or declaration is objected to be	3 is/are: a) ☐ accepted or b) ☒ obtion to the drawing(s) be held in abeyangle correction is required if the drawing	nce. See 37 CFR 1.85(a). (s) is objected to. See 37 CFR 1.121(d).				
Priority under 35 U.S.C. § 119						
12) Acknowledgment is made of a claim for a) All b) Some * c) None of:  1. Certified copies of the priority do 2. Certified copies of the priority do 3. Copies of the certified copies of application from the Internations * See the attached detailed Office action	ocuments have been received. ocuments have been received in A f the priority documents have been al Bureau (PCT Rule 17.2(a)).	Application No  received in this National Stage				
Attachment(s)  1) Notice of References Cited (PTO-892)		Summary (PTO-413) s)/Mail Date				
<ol> <li>Notice of Draftsperson's Patent Drawing Review (PTG3) Information Disclosure Statement(s) (PTO/SB/08)         Paper No(s)/Mail Date 1/5/04 and 9/13/04.     </li> </ol>		nformal Patent Application				

#### **DETAILED ACTION**

#### Election/Amendments

Applicants' election, without traverse, of Group I (claims 18-28) in the response filed 11/27/06 is acknowledged.

Accordingly, claims 1-35 are currently pending, elected claims 18-28 and linking claims 1-17 are under examination.

Claims 29-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made without traverse in the reply filed on 11/27/06.

### Information Disclosure Statement

The Information Disclosure Statements filed 1/5/04 and 9/13/04 have been entered and considered. Initialed copies of the form PTO-1449 are enclosed with this action.

#### **Drawings**

It is noted that at least one of the drawings filed 8/4/03 is a color photograph or color drawing. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

## Specification

The specification is objected to because of the following including informalities:

The title of the invention is not descriptive. The elected invention is drawn to a method for eliminating indistinguishable differentials from a direct comparison of data matrices. The current title, however, is directed to a method for eliminating false data from comparative data matrices and for quantifying data matrix quality. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Trademarks are used in this application, such as CY3 and CY5 on page 21. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to also because it contains an embedded hyperlink and/or other form or browser-executable code. Such code is present in the specification at page 49 and elsewhere. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP ' 608.01.

Appropriate correction is required.

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Claim Rejections-35 USC § 101

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-28 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are drawn to a method for eliminating indistinguishable differentials from a comparison of data matrices, comprising: (a) ranking the data points of each matrix from highest to lowest according to intensity such that a plot of rank versus intensity of the data points for each matrix provides an experimental curve for each matrix; (b) fitting a smooth curve to each experimental curve to provide a model curve for each matrix, each model curve comprising a first section separated from a second section by an inflection point; (c) eliminating any pair of corresponding data points for which each data point of the pair is below the inflection point of its model curve; and (d) eliminating any pair of corresponding data points for which the rank of each data point of the pair is below a selected cutoff rank.

The following analysis of facts of this particular patent application follows the rationale suggested in the "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (OG Notices: 22 November 2005, available from the US PTO website at http://www.uspto.gov/web/offices/com/sol/og/2005/week47/og200547.htm).

The Guidelines states:

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To satisfy section 101 requirements, the claim must be for a practical application of the  $\S$  101 judicial exception, which can be identified in various ways (Guidelines, p. 19):

- The claimed invention "transforms" an article or physical object to a different state or thing.
- The claimed invention otherwise produces a useful, concrete and tangible result, based on the factors discussed below.

In the instant case, at least one embodiment of the claimed invention merely manipulates data sequences and performs a series of calculations without transforming an article or physical object to a different state or thing outside a computation device.

Furthermore, the invention does not produce a useful, concrete and tangible result. Specifically, it does not produce a tangible result. Since the process merely manipulates data sequences and performs a series of calculations, and the process can be performed entirely in a computer or machine or human mind without using or making available for use the results of the manipulation to enable its functionality and usefulness to be realized.

# Claim Rejections-35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "a method for eliminating indistinguishable differentials" in the preamble.

The metes and bounds of the claimed invention are not clear because it is unclear what is meant
by indistinguishable differentials and it is not clear from what the differentials are

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indistinguishable. Furthermore, the method steps do not recite such a limitation, and thus it is not clear whether it is required as part of the invention and how it is achieved if it is.

Claim 1 recites "ranking the data points from highest to lowest according to intensity" in step (a). The metes and bounds of the claimed invention are not clear because it is unclear what is meant by intensity of data. Data, per se, do not have intensity.

Claim 1, at line 5 of step (d) recites "on the model curve." The phrase lacks clear antecedent basis because there is prior reference to at least two model curves: a model curve for each matrix and thus two model curves for the two matrices. It is thus unclear which of the two curves is referred to by the phrase "the model curve." This same phrase, which also lacks clear antecedent basis for the same reasons, is also recited in line 5, 6, and 7 of claim 2, line 2 of claim 3, line 2 of claim 4, line 2 of claim 5, and line 2 of claim 6.

Claim 2 recites an equation having variables including "C," which is not defined.

Claim 2 at line 6 recites "CR," but it is not in the equation and is also not defined.

Claim 7 recites an equation including " $a_1$ , ...,  $a_{19}$ ," which are defined as "variables." The metes and bounds of the claimed invention are not clear because it is unclear what the variables are.

Claim 7 recites "in the data matrix" at line 6. The phrase lacks clear antecedent basis because there is prior reference to at least two data matrices in claim 1 from which claim 7 depends, and it is thus unclear which data matrix is referred to by "the data matrix."

Claim 13 recites "expression levels of biomolecules." The metes and bounds of the claimed invention are not clear because it is unclear what is precisely meant by the phrase "expression levels." Biomolecules, absent an explicit definition in the specification, are molecules present in biological samples such as nucleic acids, proteins, carbohydrates, fatty acids, etc. It is know nucleic acids can be expressed, i.e. DNA being transcribed, RNA being translated. However, it is unclear how a carbohydrate or fatty acid molecule can be expressed.

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Claim 17 recites "oligonucleotide expression levels." The metes and bounds of the claimed invention are not clear because it is unclear what is meant by "oligonucleotide expression levels."

Claim 18 recites "a method for eliminating false differentials" in the preamble. The metes and bounds of the claimed invention are not clear because it is unclear what is meant by false differentials absent a definition for the term in the specification. Furthermore, the method steps do not recite such a limitation, and thus it is not clear whether it is required as part of the invention and how it is achieved if it is.

Claim 18 recites "eliminating indistinguishable differentials from the data matrices according to the method of claim 1. The metes and bounds of the claimed invention are not clear because it is unclear what is meant by indistinguishable differentials and it is not clear from what the differentials are indistinguishable. Furthermore, the method steps of claim 1 do not recite such a limitation, and thus it is not clear whether it is required as part of the invention and how it is achieved if it is.

Clarification of the metes and bounds of the claims is requested.

#### Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shubo (Joe) Zhou, whose telephone number is 571-272-0724. The examiner can normally be reached Monday-Friday from 8 A.M. to 4 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem (Remy) Yucel, Ph.D., can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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SHUBO (JOE) ZHOU, PH.D.
PATENT EXAMINER